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Mastoid Obliteration with S53P4 Bioactive Glass Can Make Bonebridge Implantation Feasible: A Case Report

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Manuscript Preparation E
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ABCDEF 1,2,4,5

Bartłomiej Król
Marek Porowski
Katarzyna B. Cywka
Magdalena B. Skarżyńska
Piotr Henryk Skarżyński

1 World Hearing Center, Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany, Poland
2 Oto-Rhino-Laryngology Surgery Clinic, World Hearing Center, Institute of Physiology and Pathology of Hearing, Warsaw/Kajetany, Poland
3 Institute of Sensory Organs, Warsaw/Kajetany, Poland
4 Center of Hearing and Speech Medincus, Warsaw/Kajetany, Poland
5 Department of Heart Failure and Cardiac Rehabilitation, 2nd Faculty of Medicine, Medical University of Warsaw, Warsaw, Poland

Corresponding Author: Piotr Henryk Skarżyński, e-mail: p.skarzynski@ifps.org.pl

Conflict of interest: None declared

Patient: Male, 41-year-old
Final Diagnosis: Bilateral otitis media with cholesteatoma
Symptoms: Hearing loss
Medication: —
Clinical Procedure: —
Specialty: Otolaryngology

Objective: Unusual or unexpected effect of treatment

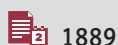
Background: Obliteration of the mastoid cavity with S53P4 bioactive glass is becoming a popular method of treatment, allowing most of the problems with the postoperative cavity to be eliminated. In the case of a hearing aid, reconstruction of the posterior wall of the auditory canal is an extremely beneficial procedure and, in the case of the Bonebridge implant, is necessary. After reconstruction, the FMT transducer is covered by bone and bioactive glass and has no contact with the postoperative cavity. The aim of this article is to present a case report.

Case Report: A 41-year-old male patient with a history of bilateral otitis media with cholesteatoma since childhood had undergone many ear operations since 2001, including radical modified operations and postoperative revisions. There had been ossiculoplasty using own materials and a Kurz TORP prosthesis which gave a short-term hearing improvement for 3 months. The patient underwent tests for implantable devices, which showed a potential significant improvement in hearing and understanding speech. The patient met the audiological criteria qualifying him for the use of an implantable bone conduction device. However, a CT scan of the temporal bone showed that the Bonebridge implant could not be implanted due to insufficient mastoid volume. In order to safely implant the Bonebridge device, it was necessary to first rebuild the posterior wall of the left ear canal. The absolute condition was no inflammation of the ear or leaks for several months.

Conclusions: The two-stage surgical procedure as described in this case report can allow the Bonebridge implant to be used in a wider group of patients with previous anatomical limitations.

MeSH Keywords: Bone Conduction • Cholesteatoma • Hearing Loss

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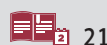
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Background

Patients with chronic otitis media with cholesteatoma require surgery, and canal wall-down surgery (CWD) is necessary in advanced cases [1]. Hearing loss is a common complication after surgery, especially in advanced cases [2,3]. If classical reconstruction is used, and use is made of the patient's own tissue or a passive prosthesis, it is then possible to use an implantable device [4,5]. When an implant is used, in addition to audiological criteria, anatomical criteria must also be met [6,7].

Due to its auditory benefits and aesthetics, the Bonebridge implant seems to be an optimal device for patients with conductive hearing loss and some cases of mixed hearing loss. However, in some cases it is not possible to safely place the Bonebridge implant due to previous CWD surgery. In such patients, reconstruction of the posterior wall of the external auditory canal using Bonalive bioactive glass S53P4 may be considered [8].

Case Report

A 41-year-old male patient with a history of bilateral otitis media with cholesteatoma since childhood had been under the care of the Institute of Physiology and Pathology of Hearing. He had undergone many ear operations (3 right ear and 3 left ear) since 2001 due to recurrent leakage from both ears, including radical modified operations and subsequent revisions. There had been ossiculoplasty using own materials and a Kurz TORP prosthesis which gave short-term hearing improvement for 3 months.

The patient underwent tests for implantable devices, and a simulation of the use of an implant using bone conduction was performed using a sound processor on softband. Audiometric tests were performed (pure-tone audiometry, free-field audiometry, and speech audiometry in quiet and noise), which showed a potential significant improvement in hearing and understanding speech. The patient met the audiological criteria qualifying him for use of an implantable bone conduction device (Figure 1). However, a CT scan of the temporal bone showed that the Bonebridge implant could not be implanted due to insufficient mastoid volume. The FMT transducer must be covered by bone without contact with the CWD postoperative cave. Our center does not perform surgery placing the Bonebridge implant outside the mastoid process, behind the sigmoid sinus. Surgeons generally try to avoid placing the implant on the dura; however, in some centers this solution is used [9]. In some cases, there is need to release a very thin bone wall between the device and dura or sigmoid sinus (so they could be compressed).

To safely implant the Bonebridge device, it was necessary to first rebuild the posterior wall of the left ear canal. The absolute condition was no inflammation of the ear or leaks for several months (final grade '0' in Merchant's grading system).

Before qualifying for surgery, a thorough otoscopic assessment of the postoperative cavity was performed and a control swab was taken (with negative results). Then, under general anesthesia, obliteration of the left mastoid was performed. A retroauricular incision was made, followed by coagulation of bleeding vessels. The postoperative cavity was detached and the epidermis

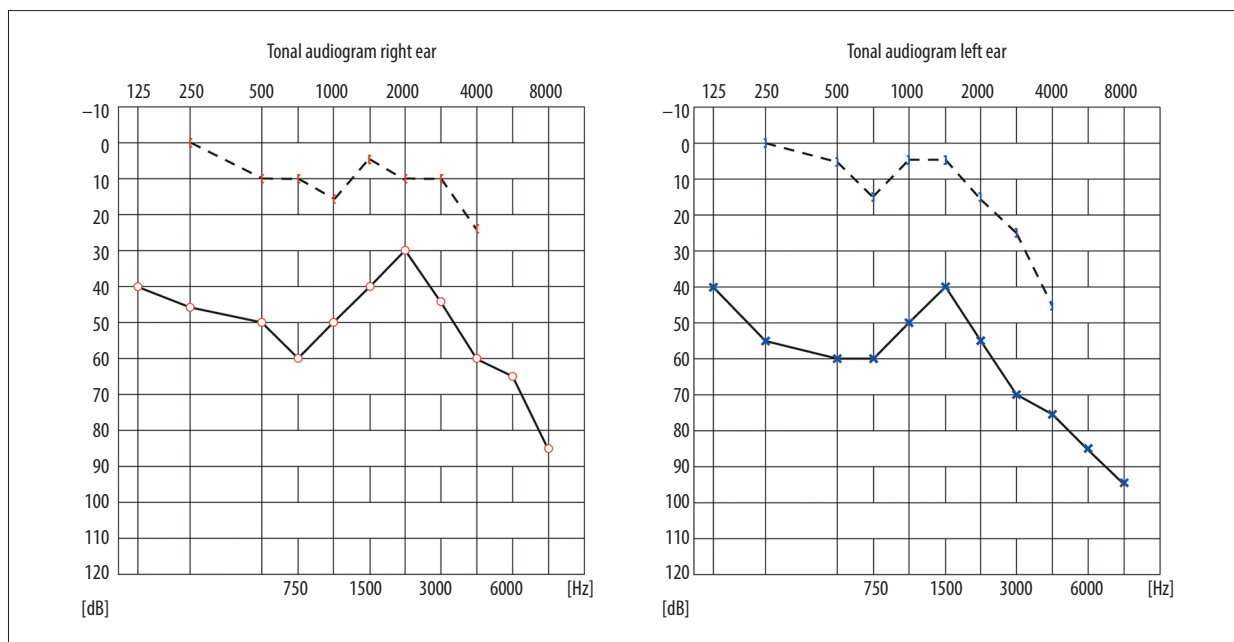


Figure 1. Pure-tone audiometry before implantation.

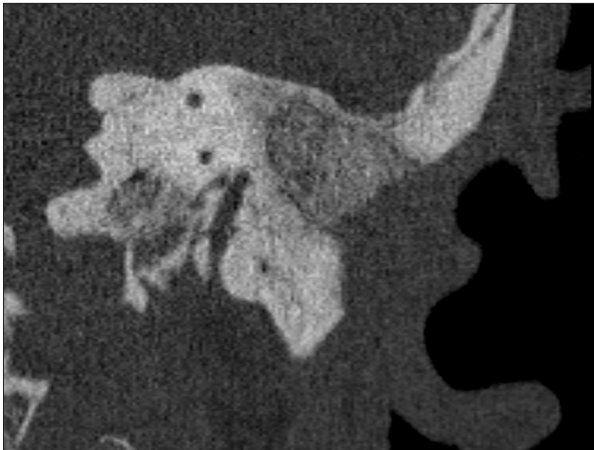


Figure 2. Healed reconstruction of the posterior wall of the external auditory canal with bioactive glass S53P4 (left ear).

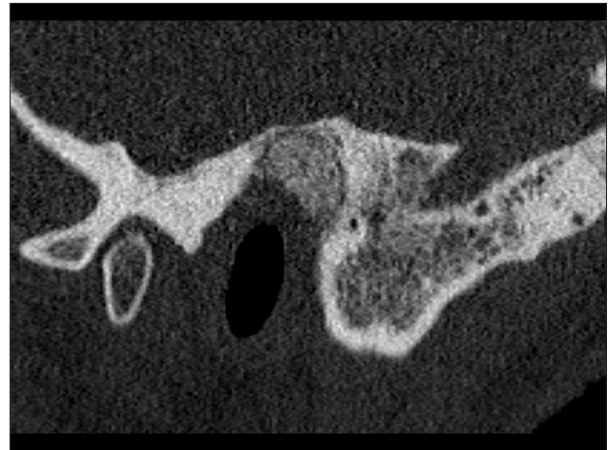


Figure 3. Healed reconstruction of the posterior wall of the external auditory canal with bioactive glass S53P4 (left ear).

covering the cavity was raised. Using a diamond cutter, the cavity was smoothed and the epidermis and post-inflammatory lesions were removed. A fragment of the periosteum and cartilage was removed from a section of the auricle, and sutures were put in place. Using the collected material, the posterior wall of the external auditory canal was reconstructed and then stabilized with tissue glue. The cavity was filled with granules of the bioactive material S53P4 Bonalive (about 0.8 cm³). Subcutaneous and skin sutures were applied, followed by a dressing of silicon foil, Fluocinolone acetonide+Neomycin sulfate filters, and an external dressing. After the procedure, the patient felt well and was placed under observation, receiving Cefazolin 1000 mg intravenously twice daily and pain medication. The patient was discharged in good general condition, receiving the antibiotic amoxicillin (875 mg) with clavulanic acid (125 mg) in 1000-mg tablets twice a day for 7 consecutive days (14 doses in all).

After 7 days, the dressing was removed from the ear, as were the sutures from the retroauricular incision. Correct healing was found. Thirty days after surgery, the patient had no complaints. There was good local healing, insignificant serous discharge, and a dry epidermis. The area was cleaned, a control swab was taken, and pure-tone audiometry was conducted. Microbiological testing indicated no growth of bacteria or fungi. At subsequent visits 3 and 6 months later, otoscopy showed proper healing. Air and bone conduction thresholds showed results comparable to those before surgery. Six months after the procedure, a CT scan of the temporal bones was performed, showing a correctly healed. Bonalive reconstruction and sufficient conditions for Bonebridge implantation on the left side.

Consequently, a Bonebridge implantation was performed. An 'S' retroauricular cut was made, and the subcutaneous tissues were displaced until the periosteum was reached. Moderate bleeding from an emissary vein was managed by coagulation.

An opening was made in the mastoid in place of the previous filling with Bonalive material. Its size corresponded to the Bonebridge template. The created cavity did not contact the dura or sigmoid sinus. After confirming the implant fit in the correct position, the operating cavity was rinsed from bone fillings and 2 holes were made through the template using a custom drill. The thickness of the skin flap was normal (it should be between 0.3 mm to 0.8 mm). The Bonebridge implant was adjusted in the previously created cavity, and the plastic part of the implant was bent through 60 degrees. The implant was attached using 2 custom-made screws. After checking the correct position of the implant, 2 layers of subcutaneous and 1 skin layer sutures were applied. A dressing of Exmoor foil, Fluocinolone acetonide+Neomycin sulfate filter sponge, and an external dressing were applied. After the procedure, the patient had no symptoms and was placed under observation. He received Cefazolin 1000 mg intravenously twice daily and pain medication. He was discharged in good general condition, and received amoxicillin (875 mg) with clavulanic acid (125 mg) in 1000-mg tablets twice a day for 7 consecutive days. Antibiotic use was according to clinical recommendation, but there is no general consensus on that topic and some clinics give only 1 dose of antibiotic during surgery. After this time, the dressing was removed, as well as sutures from the retroauricular incision. Good healing was found. After 30 days, an otoscopic examination showed normal healing and a CT scan of the temporal bone was performed. The cured reconstruction of the back wall of the external auditory canal with S53P4 bioactive glass is shown in Figures 2 and 3.

Five weeks after the operation, the device was activated and the settings adjusted to the audiometric test results and the patient's subjective assessment. To assess the auditory benefits from the Bonebridge, audiometric tests were performed: pure-tone audiometry, free-field audiometry, and speech understanding in quiet

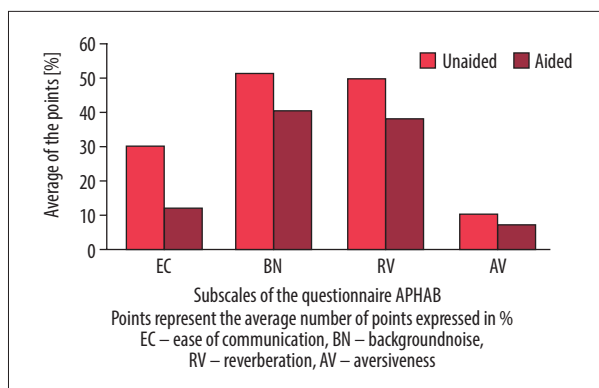


Figure 4. Comparison of APHAB results before (unaided) and after (aided) implantation.

and noise (matrix sentence test). Pure-tone audiometry showed that the average gain for air conduction was 24 dB. There was also a significant increase in speech discrimination in noise (matrix sentence test): without the device the patient's result was 5.8 dB SNR, and with the implant it was -0.7 dB SNR. To assess the auditory benefits of using the implant, the patient completed an APHAB questionnaire (Abbreviated Profile of Hearing Aid Benefit). On all parts of the questionnaire (Ease of Communication, EC; Reverberation, RV; Background Noise, BN; and Aversiveness, AV), a lower level of hearing problems was noted (Figure 4).

Discussion

Obliteration of the mastoid cavity has been a challenge in otosurgery for years. Natural and autologous materials have been used for over a century, using bone chips, cartilage, fat, muscle lobes, or fascia [10,11]. However, these tissues often tend to shrink and rapidly resorb [12], resulting in a lack of the desired effect, especially for large postoperative defects. Other research describes the possibility of using cortical bone chips [13], but our center does not perform such surgeries. This approach would require greater periosteal detachment and removal of chips from the remaining bone, which is not recommended for a Bonebridge implant. Studies prove the safety and effectiveness of obliteration of the cavity after radical surgery with bioactive glass S53P4 [14,15]. Elimination of the cavity and its complete closure reduces the risk of accumulation of ear wax and epidermis, and thus prevents recurrent inflammation of the ears. Check-up otoscopies are therefore less frequent and the patient does not need to protect the ear from water [16]. We conclude that in the absence of other health contraindications, obliteration of the mastoid cavity can be performed after canal wall-down surgery to improve a patient's quality of life [17].

In some patients after radical surgery, anatomical conditions partially or completely eliminate the option of using a Bonebridge implant; due to the postoperative cavity, the volume

of the mastoid is insufficient to hold the BC FMT transducer. Reconstruction of the posterior wall of the external auditory canal with S53P4 bioactive glass creates anatomical conditions suitable for Bonebridge implantation. After reconstruction with Bonalive, a CT scan of the temporal bone should be performed to assess healing [18] and the anatomical conditions surrounding the implant. Temporal bone with reconstruction should be thick enough to cover the BC FMT, without contact with the sigmoid sinus and dura. A CT performed immediately after implantation will contain artifacts that prevent accurate assessment of the surgical site, so healing time is needed.

The Bonebridge implant is designed for patients with conductive or mixed hearing loss whose bone conduction threshold does not exceed 45 dB [19]. The device consists of 2 elements: (1) an outer part called the sound processor (SAMBA) and (2) an implantable part consisting of the active bone conduction implant BCI 601 containing an internal coil, a magnet to hold the audio processor in place over the implant, a demodulator to convert the signal from the audio processor, and a BONE Conduction Floating Mass Transducer (BC FMT) to cause vibrations of the skull. The coil receives electronic signals from the audio processor and converts them into mechanical sound vibrations. These vibrations are directly conducted through the bone to the cochlea. The BCI is implanted in the mastoid and temporal region of the ear. Bonebridge BCI 601 is the world's first active implant based on bone conduction [20]. Its advantage is the ability to directly transfer sound through the bone of the skull to the inner ear. Unlike other implants, Bonebridge permits the surrounding skin to remain intact, minimizing risk of irritation. Another advantage of the device is the ability to perform an MRI examination (up to 1.5 T). Direct inner-ear stimulation provides natural sound perception and free communication with the environment [21].

Mastoid cavity obliteration with S53P4 bioactive glass also enables safe use of conventional hearing aids. However, Bonebridge implantation allows continuous ventilation of the ear, avoids the occlusion effect, and provides better sound quality. Each patient should be considered as an individual case.

Conclusions

In the case presented, we used an additional surgical procedure to reconstruct the posterior wall of the external auditory canal using Bonalive S53P4. Creating anatomical conditions suitable for safe placement of the BC FMT implant allowed the option of using the Bonebridge device. The two-stage surgical procedure as described in this case report can allow the Bonebridge implant to be used in a wider group of patients. Previously, these patients, although they did have the necessary audiological criteria, had anatomical limitations which prevented implantation.

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